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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------------|--------------------------------------|----------------------|---------------------|------------------|
| 10/590,125 | 06/04/2007 | Andre Schlienger | 10139/04302 | 4059 |
| ⁷⁶⁹⁶⁰ Fay Kaplun & N | 7590 07/13/201 Marcin. LLP | 1 | EXAMINER | |
| 150 Broadway, | suite 702 | | COTRONEO, STEVEN J | |
| New York, NY 10038 | | | ART UNIT | PAPER NUMBER |
| | | | 3733 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 07/13/2011 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | Application No. | Applicant(s) | | | | |
|--|---|---------------------------------------|--------------------|--|--|--|--|
| Office Action Summary | | 10/590,125 | SCHLIENGER ET AL. | | | | |
| | | Examiner | Art Unit | | | | |
| | | STEVEN COTRONEO | 3733 | | | | |
| Period fo | The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | |
| Status | | | | | | | |
| 1) ズ | Responsive to communication(s) filed on 03 Ma | av 2011 | | | | | |
| • | | action is non-final. | | | | | |
| 3) | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| ٠,١ | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| | · | , , , , , , , , , , , , , , , , , , , | | | | | |
| Disposit | ion of Claims | | | | | | |
| 4) 🛛 | Claim(s) <u>12-24</u> is/are pending in the application. | | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| | 5) Claim(s) is/are allowed. | | | | | | |
| 6) 🖾 | Claim(s) <u>12-24</u> is/are rejected. | | | | | | |
| 7) | Claim(s) is/are objected to. | | | | | | |
| 8) | Claim(s) are subject to restriction and/or | election requirement. | | | | | |
| Application Papers | | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | | |
| | Applicant may not request that any objection to the o | drawing(s) be held in abeyance. Se | ee 37 CFR 1.85(a). | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority ι | under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| Attachment(s) | | | | | | | |
| | ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) | y (PTO-413) Date | | | | | |
| 3) 🔲 Infor | re of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) er No(s)/Mail Date | 5) Notice of Informal 6) Other: | | | | | |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perry (US 5,766,174) in view of Frigg et al. (US 5,041,115) and in view of Buhren et al (WO 00/06039 see US 6,547,791 for English translation) further in view of Leu et al. (US 6,270,499).

Perry discloses an intramedullary nail comprising: an elongated nail body having a proximal end, a distal end for insertion into the medullary canal, a central axis and a total length L; a proximal locking section (fig 4, 32), distal locking section (fig 4, 36), and isthmus locking section (fig 4,34) spaced along the length of the nail body, the proximal locking section nearest the proximal end, the distal locking section nearest the distal end, and the isthmus locking section located between the proximal and distal locking sections, and each locking section including a through- hole for receiving a locking screw; a first intermediate section (see fig 4 below) separating the proximal and isthmus locking sections, and a second intermediate section (see fig 4 below) separating the isthmus and distal locking sections, each intermediate sections having fewer through-

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holes per unit length than the locking sections. The intermediate section has no through holes (fig 1).

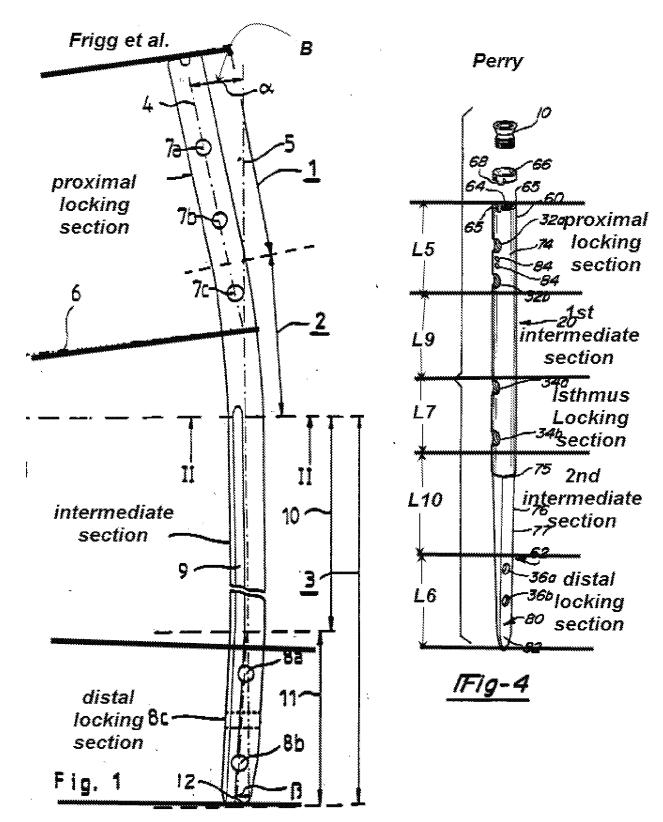
Perry does not disclose wherein the proximal locking section forms an angle B with the intermediate section, where B is in the range of 7° < B < 13° and does not disclose the proximal locking section comprising an elongated through hole.

Frigg et al. a proximal locking section forms an angle B with the intermediate section (see fig 1 below), where B is in the range of 7° < B < 13° (col. 4 II. 40-42, "8 to about 18 degrees") to allow for use in the tibia (abstract).

Buhren et al. discloses a proximal locking section comprising an elongated hole (fig 1, 32) to allow for the use of dynamic or compression locking bolts (US version col. 2 II. 58-59)

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the device of Perry with the proximal locking section forming an angle B with the intermediate section, where B is in the range of 7° < B < 13° in view of Frigg et al. in order to allow for use in the tibia and it would haven been obvious at the time of the invention to one of ordinary skill in the art to modify the device of Perry with the proximal locking section comprising an elongated hole in view of Buhren et al. in order to allow for the use of dynamic or compression locking bolts.

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As to claims 14 to 19, Perry in view of Frigg et al. and in view of Buhren discloses the claimed invention except for L5 is between .22L and .28L; L6 is between .18L and .22L; L7 is between .08L and .15L; L9 is between .27L and .33L; L10 is between .13L and .30L; and L10 plus L6 is between .32L and .5L. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device with L5 is between .22L and .28L; L6 is between .18L and .22L; L7 is between .08L and .15L; L9 is between .27L and .33L; L10 is between .13L and .30L; and L10 plus L6 is between .32L and .5L, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Perry in view of Frigg et al. and in view of Buhren et al. discloses the claimed invention except for the isthmus locking section includes two through holes arranged at a relative angle A.

Leu et al. discloses the isthmus locking section includes two through holes arranged at a relative angle A (see fig 1 below) to allow accurate positioning of the intramedullary nail in the intramedullary space (col. 3, II. 60-63).

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the device of Perry in view of Frigg et al. and in view of Buhren et al. with the isthmus locking section includes two through holes arranged at a relative angle in view of Leu et al. in order to allow accurate positioning of the intramedullary nail in the intramedullary space.

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Perry in view of Frigg et al. and in view of Buhren et al. in view of Leu et al. discloses the claimed invention except for the relative angle being 90 degrees. The angle between Leu et al. through holes 7 is not disclosed in the specification but appear to be around 90 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the relative angle being 90 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

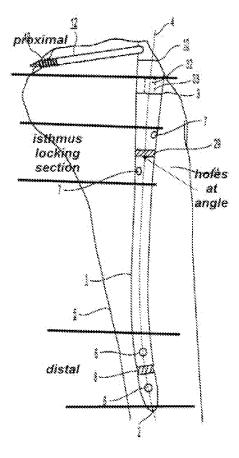


Fig. 1

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Response to Arguments

Applicant's arguments, see Remarks, filed 5/3/2011, with respect to the U.S.C. 112 rejection of claim 25 have been fully considered. The U.S.C. 112 rejection of claim 25 has been withdrawn because claim 25 is cancelled.

Applicant's arguments filed 5/3/2011 have been fully considered but they are not persuasive. The applicant argues that the holes 7 of Leu are not analogous to an isthmus locking section stating that the holes are not placed in the middle of bone that is thinner than the ends. The examiner respectfully disagrees. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Leu is used to modify the medial holes of Perry. Perry's medial holes are clearly in the isthmus of the Perry hole. The two sets of holes are analogous because they both lie in the middle of their respective nail body.

The applicant also argues that there is no motivation to make the angular relationship between the isthmus locking holes to be 90 degrees. The examiner respectfully disagrees. Leu teaches a non-parallel relationship between the locking holes that appears to be close to 90 degrees. It would also be obvious to one of ordinary skill in the art to achieve a 90 degree hole by trial and error to find the best arrangement for increasing the purchase of bone (as stated in the pervious office action on page 8).

The applicant also argues one wouldn't change the angle of the holes in Perry because one would not definitively know where the holes would be. The examiner respectfully disagrees. The location would be known if the angle is known between the two holes. A 90 degree arrangement would be advantageous as stated above to increase the purchase to the bone.

The rejection is deemed proper.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEVEN COTRONEO whose telephone number is (571)270-7388. The examiner can normally be reached on M-F 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. C./
Examiner, Art Unit 3733
/EDUARDO C. ROBERT/
Supervisory Patent Examiner, Art Unit 3733